

## **REMARKS**

### **Amendments**

New claims 40 and 41 are directed to the elected Group. See, e.g., page 15, lines 11-30.

### **Information Disclosure Statement**

In the Reply filed December 29, 2008, applicants requested the Examiner acknowledge consideration of the English language abstract of JP 09-227,523. For the Examiner's convenience, a form PTO/SB/08A listing the document, and a copy of the English language version of the International Search Report were provided with the Reply filed December 29, 2008.

For the reasons discussed in the Reply filed December 29, 2008, applicants respectfully request the Examiner to initial the form PTO/SB/08A indicating that the English language abstract of JP 09-227,523 has been considered, and return to applicant an initialed copy of the form PTO/SB/08A with the next Office Action.

### **Election and Traversal of Restriction Requirement**

In response to the Restriction Requirement presented in the January 11, 2010 Office Action, applicants hereby elect Group XI, i.e., claims 1-13, 15-19, 22, 25, 26, 28, 30, 31, and 34-38, wherein D is phenyl and T is piperidine. **However, it is noted that claims 20, 21, 32, and 33, and new claims 40-41, also read on this subject matter and thus should be included in the examination of elected Group XI.**

In response to the election of species requirement, applicants hereby select the compound (R)-1-(4-chlorophenyl)-3-[2-(1'-methyl-4,4'-bipiperidinyl-1-yl)-2-oxo-1-phenylethyl]urea. See the first compound recited in claim 21 and the compound disclosed in Example 1 in the specification. Claims 1-13, 15-19-22, 25, 26, 28, 30-38, 40, and 41 read on the elected species. However, the Restriction Requirement is traversed.

In the Restriction, applicants' compound genus is divided into 5 Groups, depending on the definitions of the variable groups D and T. While overall the claims are divided into 15 Groups, Groups I-V, VI-X, and XI-XV involve the same compound subject matter,

respectively, but differ with respect to the methods of use included within each group.

37 CFR 1.475(a) states that a national stage application shall relate to either one invention only or to “a group of inventions so linked as to form a single general inventive concept (‘requirement of unity of invention’).” Thus, the requirement of “a single general inventive concept” is directed to the situation where a group of inventions are presented. The Rule further states that for such a situation, i.e., where a group of inventions is involved:

the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Applicants’ claim 1 is a Markush claim. A Markush claim is not a group of inventions such as a product, a process specially adapted for the manufacture of the product, and a use of the product. The Markush claim is directed to a single invention, i.e., a genus of compounds. Thus, it is not necessary to show a “special technical feature” that defines “a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.”

In any event, Annex B (entitled UNITY OF INVENTION) of the Administrative Instructions Under the PCT specifically sets for the manner for dealing with Markush claims in applications resulting from PCT applications. Section (d) of Annex B states that there are “three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail.” Section (d) further states that the principles for interpretation of PCT Rule 13.2 in these “three particular situations” are set out in subsequent sections, and that these principles for interpretation **are, in all instances, interpretations of the requirements of Rule 13.2.**

One of these “particular situations” is the situation of a Markush claim, and the principles for interpretation of this situation are set forth in section (f) of Annex B:

(f) “**Markush Practice**”. The situation involving the so-called “Markush practice” wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding

special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

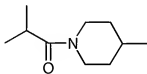
(A) all alternatives have a common property or activity, and

(B) (1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

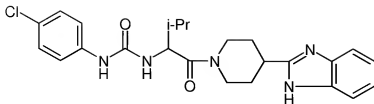
(B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

Thus, as can be seen from the above, a Markush grouping (such as presented in the instant claims) will satisfy PCT rule 13.2 if the alternatives share a common property or activity and there is a significant common structural element shared by the alternatives.

Applicants' compounds share a common activity or property as discussed in applicants' specification. For example, the compounds exhibit factor Xa-inhibiting properties, and inhibitory activity with respect to coagulation factor VIIa, factor IXa, and thrombin in the blood coagulation cascade. See, e.g., page 4, lines 1-112 of applicants' specification. Additionally, the alternatives of the Markush grouping share a common significant structure, namely a central piperidinyl ring. In pending claim 1, groups Z, Z' and E are not variable groups, and these groups together with the N atom form a piperidine ring. Additionally, the common core structure also exhibits a carboxamide group. This overall common core structure is illustrated by the following subformula:



In the Office Action issued January 11, 2010, it is argued that applicants' claims lack a "corresponding special technical feature" due to the disclosure of the compound with CAS Registry No. 330161-52-9. This compound has the following structure:



Similarly, it is argued in the Decision on Petition issued December 24, 2009 that the common core structure of applicants' claimed compounds, as illustrated above, is present in compounds of WO 03/050199. See page 6 of the Decision on Petition.

However, as discussed above, the principles for interpretation of PCT Rule 13.2 as it relates to Markush claims do not require that the core structure of the claimed genus compounds distinguish over the art. Moreover, as discussed further below, imposing such a requirement is contrary to US law.

In the Decision on Petition, the Petitions Examiner asserted that applicants' arguments with respect to MPEP §803.02, *In re Harnish*, 206 USPQ 300 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d (Bd. Pat. App. & Int. 1984) do not relate to applications filed under the provisions of 35 USC §371. Applicants disagree.

Applications filed under the provisions of 35 USC §371 are still US patent applications and thus are subject to the statutes under Title 35. MPEP §803.02, and the Court decisions *In re Harnish*, 206 USPQ 300 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d (Bd. Pat. App. & Int. 1984), relate to interpretations of US law, namely 35 USC §121. Therefore, this section of the MPEP and these court decisions apply to US patent applications, including national phase applications filed under the provisions of 35 USC §371. In addition, as discussed further below, the court's decision in *In re Harnish* clearly demonstrates that requiring a Markush claim to exhibit a core structure which distinguishes over the prior art is contrary to US law, namely 35 USC §121 as that law has been interpreted by the courts.

35 USC §121 does not permit restriction within a single claim as clearly indicated by the court in *In re Weber et al.*, 198 USPQ 328 (1978).

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he

considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits.

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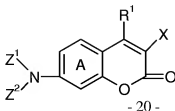
It is apparent that §121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to *reject* a particular claim on that same basis. [*Weber* at 331-332]

The effect of restriction within a single claim is the same as a rejection. 35 USC §121 does not give the Commissioner authority to require that a single claim "be divided up and presented in several applications" and thus deny the Applicant the right to have that single claim considered on its merits. This is exactly the action that the Court in *Weber* stated was not permitted under 35 USC §121. Such action by an Examiner would violate "the basic right of the Applicant to claim his invention as he chooses." [*Weber* at 332]

With respect to Markush claims, MPEP §803, entitled "Restriction - When Proper," states that "[i]nsofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria are set forth in MPEP §803.02." The latter section of the MPEP states that: "[s]ince the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention." (emphasis added)

Thereafter, the MPEP cites *In re Harnish* and *Ex parte Hozumi*. As discussed previously, these two cases both deal with improper Markush rejections. Thus, in the case of Markush claims, refusal by the Office to examine that which the applicants regard as their invention must be a refusal based on an improper Markush rejection.

In this regard, the decision in *In re Harnish*, 206 USPQ 300 (CCPA 1980) is relevant. In *Harnish*, the claimed genus of compounds was defined by the following formula:



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In reversing an improper Markush rejection, the Court in *Harnisch* noted that the claimed compounds were dyes and that the claimed genus of compounds all exhibited a **coumarin ring structure, a core structure known within the art**. As the core structure was known and readily recognizable to one skilled in the art, the Markush grouping was found not to be repugnant to scientific classification.

In view of the above remarks, applicant respectfully request withdrawal of the Restriction with respect to the dividing up of claim 1 into several Groups. Specifically, applicants request that Groups XII-XV be examined with elected Group XI, that Groups I-V be combined for examination together, and the Groups VI-X be combined for examination together.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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